Image AF/1646

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re Patent Application of<br>Avi J. ASHKENZAI et al. | Examiner:<br>C. Kaufman |
| Serial No.<br>09/894,924 | Docket No.:<br>22338-00801 |
| Filed:<br>June 28, 2001 | Group Art Unit:<br>1646 |
| For: DcR3 POLYPEPTIDE, A TNFR HOMOLOG | |

**APPEAL BRIEF UNDER 37 CFR §1.192(c) WITH TABLE OF CONTENTS AND PETITION FOR ONE-MONTH EXTENSION OF TIME UNDER 37 CFR §1.136(a) TRANSMITTAL**

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Sir:

Pursuant to the Notice of Appeal filed December 11, 2003, Applicants hereby accompany the enclosed Appeal Brief for the Appellant with Table of Contents under 37 CFR §1.192 with the requisite Appeal Brief fee of $330.00 under 37 CFR §1.17(c), and an extension of time fee of $110.00 under 37 CFR §1.136(a) for extending the period of reply one month to March 11, 2004.

The Commissioner is hereby authorized to charge the $440.00 Appeal Brief and extension of time fees to Deposit Account 18-1260, and any additional fees or credit any overpayment to Deposit Account 18-1260.

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Respectfully submitted,

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202-736-8079
March 2, 2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

APPEAL BRIEF FOR THE APPELLANT

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| In re Application of<br><br>Avi J. Ashkenazi<br><br>Serial No.: 09/894,924<br><br>Filed: 06/28/2001<br><br>For: DcR3 polypeptide, a TNFR homolog | Group Art Unit: 1646<br><br>Examiner: C. Kaufman |

The Appellant believes that this brief is timely filed. Any fees required in filing this brief, including fees for extension of time, can be deducted from deposit account No. 18-1260.

The following information and arguments are provided pursuant to 37 C.F.R. § 1.192(c)

**(1) Real Party in Interest**

The real party in interest in the appeal is:

Genentech, Inc.

1 DNA Way

South San Francisco, CA 94080

## (2) Related Appeals and Interferences

The appellant is not aware of any appeals or interferences that will directly affect or will be directly affected by or have a bearing on the Board's decision in this appeal.

## (3) Status of Claims

Claims 14, 67, 69 to 72, 74 to 77 and 79 to 85 are currently pending in the application and stand finally rejected. Claims 1 to 13, 15 to 66, 68, 73 and 78 have been canceled. Claims 14, 67, 69 to 72, 74 to 77 and 79 to 85 are presently under appeal.[1]

Appellant notes claims 68, 73 and 78 were canceled pursuant to an Examiner's amendment authorized by Appellant on February 26, 2004. Such claims were indicated as being directed to allowable subject matter in the Advisory Action dated January 21, 2004, and will be pursued by Appellant in a related application. Appellant does not, by consenting to this amendment, surrender entitlement to the subject matter of the canceled claims.

## (4) Status of Amendments

There are currently no claim amendments pending.

## (5) Summary of Invention

The invention relates to antibodies that bind to a TNFR homolog designated DcR3. The invention further relates to anti-DcR3 monoclonal, chimeric, human and humanized antibodies. The invention also relates to antibodies expressed in bacterial, yeast and mammalian cell lines, and to antibodies linked to a detectable moiety such as a radioisotope, fluorescent compounds, chemiluminescent compounds and enzymes.

- Page 6, lines 26-27, discussing antibody embodiments of the invention;
- Page 10, lines 13-20, discussing the term "antibody" and "monoclonal antibody";

[1] Please note that in the Advisory Action dated 1/21/04, claims 77-84 were renumbered 78-85 because there were two claims originally numbered 77. Accordingly, the pending claims are now consecutively numbered through 85 rather than 84.

- Page 20, lines 2-10, discussing the use of antibodies for detecting the gene amplification and expression of DcR3;
- Page 26, line 5 – page 28, line 16, discussing monoclonal antibodies of DcR3 and methods of making such antibodies;
- Page 28, lines 19 – page 29, lines 19, discussing humanized and human antibodies and methods of making such antibodies;
- Page 29, lines 20 – page 30, line 16, discussing bispecific and heteroconjugate antibodies;
- Page 30, lines 18 – page 31, line 3, discussing various uses of DcR3 antibodies; and
- Example 8, discussing the preparation of antibodies that bind DcR3.

**(6) Issues**

(a) Whether claims 14, 67, 69 to 72, 74 to 77 and 79 to 85 are unpatentable under 35 U.S.C. § 102(e) over U.S. Patent No. 5,885,800 ("*Emery et al.*").

(b) Whether claim 85 is unpatentable under 35 U.S.C. § 103(a)/102(e) over *Emery et al.* in view of U.S. Patent No. 4,946,778.

**(7) Grouping of Claims**

Claims 14, 67, 69 to 72, 74 to 77 and 79 to 85 stand or fall together.

**(8) Arguments**

**(i and ii) There are no § 112 rejections at issue**

**(iii) Rejection of claims 14 and 67 to 84 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,885,800 ("*Emery et al.*")**

**(1) Summary of the rejection**

The Examiner has rejected claims 14, 67, 69 to 72, 74 to 77 and 79 to 85 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,885,800 (*Emery et al.*). In particular, the

Examiner maintains that "Emery et al. teach the TR4 polypeptide (SEQ ID NO:2) which has a sequence identical to the DcR3 polypeptide (SEQ ID NO:1) of the instant application." *See* Office Action dated 9/23/02 (Paper No. 6) at page 6. In addition, the Examiner maintains, citing the prophetic descriptions in the patent appearing at col. 3, lines 22-27, and col. 10, line 58 to col. 11, line 28, that "also taught are antibodies that bind TR4, including antibody fragments, monoclonals, polyclonals, chimeric, recombinant, and humanized antibodies, as well as methods of making the antibodies and antibody-producing host cells. *Id.* The Examiner has also rejected claim 85 under 35 U.S.C. § 103 over *Emery et al.*

The currently pending claims are directed to antibodies that bind to the expression product of certain polynucleotide sequences designated DcR3. As noted by the Examiner, the polypeptide sequence of DcR3 is the same as the TR4 polypeptide sequence. The *Emery et al.* patent contains claims directed to nucleic acids corresponding to the full length sequence designated TR4, and to nucleic acids having a high degree of homology (i.e., >90% or 95%) to the referenced sequence.

The Examiner's position is that by merely disclosing a nucleotide sequence, without disclosing any information regarding any biological role, function or activity of either the nucleotide sequence or a polypeptide encoded thereby, the *Emery et al.* disclosure fulfills the requirements for anticipation of the present claims under 35 U.S.C. § 102(e).

**(2) Appellant's observations on the scientific credibility and content of the *Emery et al.* disclosure**

Importantly, the Examiner has not contested Appellant's observed deficiencies of the *Emery et al.* disclosure, which are numerous and include the following:

- The homology analysis set forth in the *Emery et al.* disclosure is essentially meaningless to a person of skill in the art. As *Emery et al.* acknowledges, the TNF superfamily is one of the most biologically diverse families of proteins known. See, Col. 2, lines 13-15 ("effects of TNF family ligands and TNF family receptors are varied and influence numerous functions, both normal and abnormal..."). Appellant also cited publications describing the significant variation observed in ligand binding and biological roles for TNF family members. *See Locksley et al.*, "The TNF and TNF Receptor Superfamilies: Integrating Mammalian Biology," *Cell*

104:487-501 (Feb 23, 2001) and *Wallach,* "TNF Ligand and TNF/NGF Receptor Families," *Cytokine Reference*, Academic Press, pgs. 377-411 (2000) (which were both submitted for the Examiner's consideration in the IDS dated December 11, 2003.) Thus, the observed degree of homology to a member of the TNF family does not convey much meaningful information to a person of skill in the art in the absence of data characterizing some actual biological role, function and activity of the receptor. *Emery et al.* presents a highly questionable homology analysis -- both with respect to the degree and the nature of the homology. Specifically, *Emery et al.* indicate that their putative TR4 receptor shares a 29% homology to TNFR-2. *See, e.g.,* Col. 6, lines 45-55. TR4, however, is a soluble receptor which, unlike TNFR–2 (which is a membrane-bound receptor) does not have an intracellular signaling capacity. The observed homology to TNFR-2 thus conveys no meaningful information concerning the biological role, function or activity of the TR4 polypeptide.

- *Emery et al.* does not identify the ligand or ligands that actually bind to the TR4 polypeptide. Instead, *Emery et al.* lists ligands that bind to *other* members of the TNF superfamily of proteins (*See* Col. 1, lines 31-40 (in the background of the inventions section of the patent)). The ligands listed in *Emery et al.* appear to be chosen solely because they are known in the art to be ligands that bind to *other* members of the TNF family. *Emery et al* does not actually state – much less provide any data – that any of the listed ligands actually bind to the TR4 polypeptide.

- The tissue expression data in *Emery et al.* provides no guidance to a person of skill in the art to ascertain the biological role, function or activity of the TR4 polypeptide. *Emery et al.* discloses that TR4 is expressed in cDNA libraries or keratinocytes, pancreatic tumor, lung endothelium prostate, cerebellum, fetal heart, retinal pigment epithelium, and progesterone treated endometrial stromal cells, and in Northern blots of spleen, lung thymus, heart, and a neuroblastoma cell line. *See, e.g.,* Col. 6, lines 64-67; Col. 16, lines 5-40. Indeed, the *non-specific* tissue distribution data (i.e., results showing expression in varied tissues types as well as in both normal and cancerous tissues of different types) disclosed in *Emery et al.*

does not suggest or teach that the TR4 receptor can be used in any useful manner for diagnosis or treatment.

- *Emery et al.* merely speculate that the TR4 polypeptide, and TR4 antibodies, can be used in the treatment of a long and varied list of conditions from inflammation to cancer to AIDS. *See, e.g.,* Col. 2, lines 40-47; Col. 11, lines 20-27; Col. 12, lines 25-42. No support is provided in *Emery et al.* for the suggestion that the TR4 polypeptide or antibodies to it can be used in the variety of therapeutic applications recited. Indeed, *Emery et al.* appear to have based this prediction on information known about *other* TNF receptor family members, *not* the TR4 polypeptide. If anything, the recitation of such a laundry list of varied and biologically diverse conditions would suggest that *Emery et al.* in fact had no idea of what TR4 could be used for.

- The only disclosure of a "biological activity" of the TR4 polypeptide in *Emery et al.* is scientifically meaningless. For example, at Col. 3, lines 1-6, *Emery et al.* provides that:

> TR4 activity or TR4 polypeptide activity or biological activity of the TR4 or TR4 polypeptide refers to the metabolic or physiologic function of said TR4 including similar activities or improved activities or these activities with decreased undesirable side-effects. Also included are antigenic and immunogenic activities of said TR4.

This tautological description conveys no information about any *actual* biological role, function or activity of the disclosed TR4 polypeptide.

Thus, while *Emery et al.* discloses certain sequence structure information for the TR4 molecule, it utterly fails to disclose any information that would credibly describe any biological role, function or activity of the TR4 polypeptide. Instead, the disclosure speculates as to possible functions or activities that the TR4 might possess, but in a way that is so generalized and abstract as to be meaningless to a person of ordinary skill in the art. Indeed, there is no data provided in the *Emery et al.* disclosure that can reasonably establish *any* biological function or activity of the putative receptor, much less information that could establish a specific role of the nucleic acid, polypeptide, or its antibodies. Particularly for putative members of the TNF-receptor superfamily, a disclosure which provides no experimental data establishing which ligand(s) bind

to the receptor, or that otherwise does not identify some role, functions or activity of the receptor, renders the disclosure *scientifically* meaningless to a person of skill of the art.

The Examiner has not contested these observations regarding the *scientific* deficiencies of the *Emery et al.* disclosure. Instead, the Examiner has maintained that these deficiencies in *Emery et al.* do not affect its status as an anticipatory prior art reference under 35 U.S.C. §102(e). In particular, the Examiner cites § 2121.01 and § 2122 of the Manual of Patent Examining Procedure ("MPEP"), along with *In re Schoenwald,* 964 F.2d 1122 (Fed. Cir. 1992), *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968) and *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) to support and maintain the § 102(e) rejection. The Examiner also suggests that there is no legal consequence of the failure of *Emery et al.* to disclose a "utility" for a claimed invention, again, citing the above-mentioned case law.

**(3) *Emery et al.* is legally insufficient to anticipate the presented claims**

Appellant has maintained throughout the examination of this application that the scientifically deficient disclosure of *Emery et al.* renders it legally insufficient to anticipate the appealed claims. In particular, the *Emery et al* disclosure does not provide an accurate or unequivocal characterization of any biological function, activity or role of the putative receptor designated TR4, and does not disclose which ligand(s) bind to the putative receptor. Instead, it merely discloses a nucleotide sequence and speculates – inaccurately and incompletely – as to the biological function, role and activities of the putative receptor.

A critical initial inquiry to resolution of this appeal is the determination of the proper legal standard for measuring the sufficiency of a U.S. patent for anticipation under 35 U.S.C. § 102(e). Appellant submits that the proper standard is that articulated by the Court of Customs and Patent Appeals in *In re Wertheim and Mishkin*, 209 USPQ 554 (CCPA 1981); namely, that a U.S. patent can anticipate under 35 U.S.C. § 102(e) as of a particular date only to the extent that there is a sufficient disclosure under 35 U.S.C. § 112, first paragraph, for the subject matter at issue (i.e., the subject matter of the claims being rejected as being anticipated under §102(e) by the patent).[2] The Examiner appears to take the position that if the claims of the reference patent

[2] Appellant, by this argument, does not present for consideration by the Board the question of whether or not the subject matter *actually claimed* in the Emery et al., patent is supported within the meaning of § 112, first paragraph. The subject matter at issue (i.e., that being claimed in the present application) is *not claimed* in the Emery et al. patent.

are supported under § 112, the entire contents of the patent enjoy § 102(e) effect as from the filing date of the patent. As explained below, Appellant respectfully submits that this interpretation contradicts the policy underlying § 102(e) and is inconsistent with *Wertheim*.

The conceptual justification for giving a U.S. patent prior art status earlier than the date that the contents of the patent become public was first articulated in *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390, 401 (1926).[3] There, the Supreme Court reasoned that a patent owner should not be penalized for the administrative delays associated with examining and granting patents. According to *Alexander*, if a patent application could issue *claiming the subject matter at issue* on the same date it was filed—but for PTO prosecution delays—it should have prior art effect as from the date of its filing. *Id.* at 401. The critical point was that a patent could issue on the subject matter at issue.[4] Thus, under Alexander, the prior art effect of a patent disclosure is limited to that subject matter in the patent disclosure which could support a claim as required by, *inter alia,* 35 U.S.C. 112, first paragraph.[5]

In *Wertheim*, the court addressed the specific question of the effective date – for prior art purposes – to be given to a patent under 35 U.S.C. §§102(e)/103 where the patent claimed the benefit of an earlier application under 35 U.S.C. §120. The court held that the §102(e) effective

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[3] Section 102(e) was added to the patent statue as a result of the Alexander decision *See, e.g.,* Commentary on the New Patent Act, P.J. Federico, Vol. 75, No. 3, page 179, J. Pat.

[4] The Court in *Alexander* also held that "[i]t is not disputed that this [102(e)] application gave a complete and adequate description of the thing patented to Whitford, but it did not claim it." *Id* at 399; "Delays in the patent office ought not to cut down the effect of what has been done. The description [in the 102(e) reference] shows that Whitford was not the first inventor." *Id.* at 401.

[5] *See also, In re Bayer,* 568 F.2d 1357 at 1361, where the CCPA in discussing the difference between § 102(e) and § 102(b) stated:

> The concept underlying 35 U.S.C. § 102(e) is that a complete description of an applicant's invention in an earlier filed application of another, which subsequently matures into a patent, constitutes prima facie evidence that the applicant is not the first inventor of the invention in controversy. The Supreme Court in [Alexander] Milburn was of the opinion that administrative delays in the patent office should not detract from the anticipatory effect of such evidence."

date of the patent was limited to that subject matter in the patent that could satisfy the requirements of 35 U.S.C. § 112, first paragraph, relative to the claims being rejected.[6] Thus, the court recognized that a patent should be entitled to a prior art effect under § 102(e) *only as to subject matter that was disclosed in a manner that would be sufficient under § 112, first paragraph.*[7] While the specific question at issue in *Wertheim* concerned the sufficiency under § 112 of an earlier filed application to which the patent claimed priority under § 120, the logic of *Wertheim* applies with equal force to patents that do not make such priority claims.

Specifically, in *Wertheim*, the court held that in order for the patent to enjoy prior art status under § 102(e), the application to which priority is claimed must satisfy the disclosure requirements of the first paragraph of §112 for the claimed subject matter at issue. *See Wertheim* at 537. It is entirely consistent with the logic of this provision that the *actual* patent disclosure (i.e., the disclosure that is in the application that led to the patent, rather than an earlier application to which a claim under § 120 is made) must meet the requirements of § 112, first paragraph, for the subject matter being rejected.

For the numerous reasons set forth above, the *Emery et al.* patent does not provide an adequate disclosure under §112, first paragraph of the subject matter of the presently appealed claims. Indeed, applying the PTO's own guidelines concerning compliance with §112, first paragraph clearly shows that the *Emery et al.*, patent cannot support the present claims. As stated above, in the context of the TNF-receptor superfamily, the absence of any experimental data establishing the role or activity of the receptor, or biological functions associated with ligand binding to the receptor, render the disclosure of *Emery et al.* incapable of establishing a specific, substantial and credible utility for the putative receptor. Moreover, these factors, considered in light of the standards for evaluation of utility articulated in the PTO Utility Examination Guidelines (2001), render *Emery et al.* incapable of establishing a specific, substantial and credible utility for the presently claimed subject matter. Appellant notes that while there is no *per se* rule regarding homology based assertions of utility, the Guidelines direct

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[6] See, *Wertheim* at 537 ("Thus, the determinative question here is whether the invention claimed in the Pfluger patent finds a supporting disclosure in compliance with §112, as required by §120, in the 1961 Pfluger I application so as to entitle that invention in the Pfluger patent, as "prior art," to the filing date of Pfluger I. Without such support, the invention, and its accompanying disclosure, cannot be regarded as prior art as of that filing date.")

[7] *See Wertheim* at 539 ("... the application, the filing date of which is needed to make a rejection, must disclose, pursuant to §§120/112, the invention claimed in the reference patent.")

Examiners to take into account both the nature and the degree of homology recited in the application. By *Emery et al.'s* own admission, the functions of ligands and receptors in the TNF superfamily are extremely diverse. Appellant notes that the homology analysis in *Emery et al.* shows a very low degree of homology (no more than about 29%) of the putative TR4 receptor to one other member of this diverse superfamily, TNFR-2. Also as mentioned above, the nature of the homology analysis is also suspect as it compares a membrane-bound receptor (TNFR-2) with a soluble receptor (TR4). *Emery et al.* thus cannot rely on its insufficient (both in terms of the degree and nature) homology analysis, particularly in the absence of experimental data characterizing the polypeptides at issue to confirm its predictions, in order to establish a specific, substantial and credible utility for the putative TR4 receptor.

Based on substantial precedent (*See, e.g., In re Zeigler, In re Brana, and In re Fouche)*, if *Emery et al.* fails to satisfy § 101 for the presently claimed subject matter, it fails to meet the requirements of § 112, first paragraph. In particular, the insufficient disclosure in *Emery et al.* regarding the putative TR4 receptor (i.e., the disclosure does not set forth a specific, substantial and credible utility for the receptor), makes it impossible for *Emery et al.* to satisfy the "how to use" prong of § 112 for the presently claimed antibodies that bind to the receptor. Stated another way, because there is no disclosed or known use for the TR4 receptor, there is necessarily no use for antibodies that bind to the receptor. As a matter of law, then, because *Emery et al.* fails to satisfy the requirements of § 101, it fails to provide an enabling disclosure under § 112 and cannot anticipate the appealed claims under § 102(e).

In response to the Appellant's position regarding the proper legal standard for measuring the sufficiency of *Emery et al.*, the Examiner cites the cases of *In re Schoenwald, In re Hoeksema* and *In re Donohue*. Specifically, the Examiner maintains that under these cases, *Emery et al.* anticipates the present claims only if it provides a description that is sufficient to place the invention in "possession" of the public.

As an initial point, it is important to recognize that each of the cases cited by the Examiner concern the requirements of a patent or printed publication to anticipate under 35 U.S.C. § 102(b), not § 102(e). *Emery et al.* was filed prior to, but issued subsequent to, the earliest effective filing date which the Examiner has recognized for the present claims. Thus, if Emery is to qualify at all as prior art, it can qualify only under 35 U.S.C. § 102(e), not § 102(b).

Arguably, to anticipate under § 102(b), a publication must meet a different standard than what must be met to qualify as prior art under § 102(e). Specifically, under § 102(b), the publication must provide enough information that, alone or in combination with other knowledge that is in the public domain, enables one skilled in the art to either make or to use a claimed invention. *See, e.g., In re Schoenwald*, 964 F.2d 1122, 1124 (Fed. Cir. 1992); *In re Donohue*, 766 F.2d 531 (Fed. Cir. 1985). In other words, if, more than one year before an application's filing date, a publication discloses enough information (alone or in combination with other prior art) to enable one skilled in the art to make or use an invention, the public is deemed to be "in possession of" that invention and the invention cannot be novel under § 102(b). *Donohue*, 964 F.2d at 533. *See also, In re Sasse*, 629 F.2d 675 (CCPA Cir. 1980); *In re Samour*, 571 F.2d 559 (CCPA 1978). This policy concerning § 102(b) is predicated on the idea that once the public comes into possession of an invention (i.e. through public disclosure or a public use), the invention cannot be removed from the public's possession and patented.

Section 102(e), on the on the other hand, gives patents prior art status as of their filing date rather than the date of the information actually comes into the "possession" of the public. So-called "secret prior art" under § 102(e) is not actually known to the public until the date the patent issues or until the application publishes under § 122. A fundamental difference between § 102(e) and § 102(b) prior art, then, is that the public cannot be "in possession of" § 102(e) art of which it is not aware. Therefore, to be given a patent-defeating effect back to its filing date, a § 102(e) prior art patent is held to a different standard with respect to the sufficiency of its disclosure than, for example, a § 102(b) prior art patent. *See In re Bayer*, 568 F.2d 1357, 1361 (CCPA 1978) (discussing the difference between § 102(b) and § 102(e)). Thus, a patent can have a patent defeating effect under § 102(b) in some circumstances where it does not enjoy that effect as from its filing date under § 102(e). [8]

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[8] U.S. law imposes limitations on the prior art effect under § 102(e) of patents in a variety of circumstances based on public policy reasons. These limitations are each grounded on the recognition that because a U.S. patent is not a "true" public disclosure as of its filing date, it is to be accorded a different status under the law relative to a "public" document, such as a printed publication. *See,* 35 U.S.C. § 102(e)(2) (giving prior art effect to a patent based on an international application filed under the Patent Cooperation Treaty only if international application designates the United States and was published in English language). *See also, In re Hilmer,* 424 F.2d 1108 (C.C.P.A. 1970) (U.S. patent enjoys § 102(e) effect as from filing date, not from priority date claimed under 35 U.S.C. § 119 to earlier foreign filed application), *Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 784 F.2d 351, 357, 228 U.S.P.Q. 837, 837 (Fed.Cir.(Ill.) Feb 10, 1986).

Accordingly, for unclaimed subject matter to have patent defeating effect under § 102(e), the patent must provide a "complete and adequate description of the thing claimed". *Alexander Milburn,* 270 U.S. 390 at 400. Thus, consistent with *Wertheim* and *Alexander, Emery et al.* can only be entitled to a prior art effect for the currently claimed antibodies to DcR3 if it disclosed antibodies in a manner that would have permitted the grant of *claims* to such antibodies in that application. That is, in order for the *Emery et al.* patent to be anticipatory prior art under §102(e) for the presently claimed antibodies, that disclosure must comply with the requirements of § 112, first paragraph. For the reasons set forth above, clearly it does not. Accordingly, since *Emery et al.* fails to satisfy the requirements of § 112 for the subject matter of the appealed claims, it cannot anticipate these claims under § 102(e).

### (4) The Board Should Address the Important Public Policy Considerations Raised in the Present Appeal

The policies and practices of the Office in examining applications in the field of genomics make it absolutely clear that the sufficiency of disclosure of an application is a critical – if not the most critical –inquiry in the examination of these applications.[9] These policies are motivated by the apparent recognition by the Office that the disclosure of sequence information in relation to an invention in the field of genomics can be insufficient, standing alone, to support a claim (under 35 U.S.C. §§ 101 and 112) to a particular nucleic acid or to downstream inventions from that nucleic acid, such as antibodies. Indeed, in unpredictable fields of genomics and biotechnology, the disclosure of sequence information, without information derived from expression and characterization of a particular nucleic acid, provides little if any value from a scientific perspective.

Of particular importance to the present appeal is the decision of the Office to adjust its standards in 2000 regarding the requirements of 35 U.S.C. §101 and §112, first paragraph. These guidelines were motivated by and have had a clear impact on applications claiming inventions in the field of genomics. The examination guidelines and the training materials associated with those guidelines draw clear lines for applications claiming inventions in the field of genomics. Under any reasonable interpretation of those standards, the *Emery et al.* disclosure

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[9] The Office has promulgated examination guidelines that specifically address the requirements under 35 U.S.C. § 112, first paragraph (written description) and under § 101 for utility, as they pertain to inventions in the field of genomics. *See* 66 Fed. Reg. 1092 (2001).

is insufficient to support a claim for the presently claimed subject matter under §§101 and 112, first paragraph.[10]

Critically, *Emery et al.* was examined and issued *prior* to the enactment of the aforementioned guidelines and training materials. For the reasons set forth above, under the Office's *current* examination standards, *Emery et al.* is and would have been found insufficient to support claims corresponding to what is presently claimed by Appellant.[11] Under the Office's current examination standards, Emery et al., should not have issued as a patent, and cannot support – under §§ 101 and 112, first paragraph – the presently claimed invention. By doing so, the Office is, in precise contradiction to the logic of *Alexander* (which rationalizes the public policy that supports giving patents patent-defeating effect for patentable subject matter as from the filing date of the patent ) giving *Emery et al.* a prior art status for subject matter it is not entitled to have (i.e. because the presently claimed subject matter would not have been and is not patentable to *Emery et al.* based on its disclosure). Stated simply, *Emery et al.* should not be able to enjoy prior art effect under § 102(e) for subject matter that is unpatentable to *Emery et al.*

By giving the entirety of the *Emery et al.* disclosure status as prior art under § 102(e) –in particular for subject matter that is not claimed in the *Emery et al.* patent – the Office is creating an inherently unworkable legal environment that will adversely effect the biotechnology industry and patients. For example, as in the present case, the Office, by applying its current standards to the present claims, will refuse to grant Appellant patent claims concerning antibodies, despite the fact that Emery et al was not granted such claims. Thus no party will be granted patent rights in

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[10] For example, *Emery et al.* do not adequately set forth a credible, specific utility for the TR4 nucleic acids, polypeptides and derivative products (i.e., a utility that is supported by credible evidence and which is specific to that putative receptor). Instead, Emery et al., suggest that the TR4 nucleic acid and polypeptide are related to other members of the TNF superfamily, and imply that the utilities associated with other members of that family can be imputed to TR4. This assertion of only a general utility clearly falls short of the standards enunciated by the Office in the Utility Examination Guidelines (2000). Emery et al., also does not set forth a scientifically credible foundation for their assertions regarding potential utilities for the disclosed nucleic acid, polypeptide or downstream products.

[11] Indeed, the Examiner asserted in the Office Action dated September 20, 2002, that the disclosure of an application to which Appellant claims priority under 35 U.S.C. § 120 was insufficient to support the present claims, because "while the provisional priority application 60/059,288 discloses the complete DcR3 protein and encoding nucleic acid sequences, it does not disclose a specific utility for the protein." Appellant submits that the disclosure of the '288 application is more sufficient than that found in *Emery et al.*

the presently claimed subject matter. In the field of biotechnology and therapeutic development, the absence of effective patent protection will dissuade companies from pursuing development of such inventions. The impact of the Office's policies in this field, thus, can deprive the public of potential new drugs and therapeutic regimens to address unmet medical needs.

The only viable resolution of this dilemma is for the Office to construe the law governing § 102(e) so as to require a patent – when it is cited as prior art under § 102(e) –to support the subject matter defined by the *rejected* claims in a manner that complies with the requirements of § 112, first paragraph (including, *inter alia*, the requirements of § 101). Such an interpretation is consistent with the logic of applicable precedent, such as *Wertheim*, and with the Office's examination policies.[12]

**(iv) Rejection of claim 85 under 35 U.S.C. §103(a) as being obvious in view of Emery (U.S. Patent No. 5,885,800) ("*Emery et al.*") and U.S. Patent No.4,946,778 (the '778 patent)**

The Examiner has rejected claim 85 as being obvious in view of *Emery et al.* taken in view of the '778 patent.

As set forth above, the disclosure of *Emery et al.* is insufficient to anticipate the presently claimed antibodies. The '778 patent does not provide any further teachings to cure the deficiencies of *Emery et al.*, but instead is directed to methods of covalently modifying antibodies so as to attach detectable labels. The Examiner has cited the '778 patent for this purpose, and to suggest that claim 85 (to certain detectably modified antibodies) is obvious.

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[12] Appellant also notes that, to the extent that the Office takes the position that the disclosure in *Emery et al.* could be viewed as supporting a patentable claim to the subject matter of the claims rejected in the present application, a question of priority of invention will then have been raised. To the extent the Office does take such a position, it would be appropriate for the Office to declare an interference proceeding between the present application and the *Emery et al.* patent, along with any applications of Appellant that claim the same subject matter claimed in the *Emery et al.* patent (i.e., specific nucleic acid compounds) to resolve the question of priority of invention. For the reasons set forth earlier, Appellant does not believe the *Emery et al.* patent contains such a disclosure, and could not support a patentable claim that interferes with the subject matter claimed in the present application.

Because the primary reference of *Emery et al.* is insufficient for the reasons set forth above, the present rejection is improper and should be withdrawn.

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In view of the points made above regarding *Emery et al.*, Appellant believes that the pending claims 14, 67, 69 to 72, 74 to 77 and 79 to 85 are in condition for allowance and should be passed to issue. Accordingly, Appellant respectfully requests the Office to reverse the rejections of record.

Respectfully submitted,
GENENTECH, INC.

Date: March 2, 2004

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**(9) Appendix: Copy of the Claims Involved in the Appeal**

1-13 (canceled)

14. (previously amended) An isolated antibody which binds to a DcR3 polypeptide, wherein said DcR3 polypeptide (a) comprises amino acids 1 to 300 of Fig. 1 (SEQ ID NO:1) or (b) comprises amino acids 1 to X, wherein X is any one of amino acids 215 to 300 of Fig. 1 (SEQ ID NO:1).

15-66 (canceled)

67. (previously presented) The antibody of claim 14 wherein said antibody is a monoclonal antibody.

68. (canceled)

69. (previously presented) The antibody of claim 67 wherein said antibody is a chimeric antibody.

70. (previously presented) The antibody of claim 67 wherein said antibody is a human antibody.

71. (previously amended) The antibody of claim 14 wherein said antibody binds to a DcR3 polypeptide consisting of amino acids 1 to 300 of Fig. 1 (SEQ ID NO:1).

72. (previously presented) The antibody of claim 71 wherein said antibody is a monoclonal antibody.

73. (canceled)

74. (previously presented) The antibody of claim 72 wherein said antibody is a chimeric antibody.

75. (previously presented) The antibody of claim 72 wherein said antibody is a human antibody.

76. (previously amended) The antibody of claim 14 wherein said antibody binds to a DcR3 polypeptide consisting of amino acids 1 to 215 of Fig. 1 (SEQ ID NO:1).

77. (previously presented) The antibody of claim 76 wherein said antibody is a monoclonal antibody.

78. ( canceled)

79. (previously presented) The antibody of claim 77 wherein said antibody is a chimeric antibody.

80. (previously presented) The antibody of claim 77 wherein said antibody is a human antibody.

81. (previously amended) An isolated monoclonal antibody which binds to a DcR3 polypeptide consisting of amino acids 1 to 300 of Fig. 1 (SEQ ID NO:1) or consisting of amino acids 1 to 215 of Fig. 1 (SEQ ID NO:1).

82. (previously presented) The antibody of claim 80 wherein said antibody is a chimeric antibody.

83. (previously presented) The antibody of claim 80 wherein said antibody is a human antibody.

84. (previously presented) The antibody of claim 80 wherein said antibody is expressed in a recombinant host cell selected from the group consisting of a CHO cell, yeast cell and *E. coli*.

85. (previously presented) The antibody of claim 80 wherein said antibody is linked to a detectable moiety selected from the group consisting of one or more radioisotopes, fluorescent compounds, chemiluminescent compounds, and enzymes.